REMARKS

Claims 1-3, 5, 13, 15-18, 20-23, 32-36 and 39-46 are currently pending. Claims 4, 6-12, 14, 19, 24-31, 37 and 38 were previously cancelled. Claims 32 and 34-36 are currently amended and support can be found, for example, in Figs. 1 and 2. New claims 47-49 are added and support can be found, for example, in paragraph [0022]. No new matter is added.

35 USC 112, 2nd Paragraph Rejection

Claim 32, 34 and 35 are rejected under 35 U.S.C. 112, 2nd paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner states that "viewed from the distal end" is ambiguous since there are several ways to view from the distal end. The claims have been clarified to state that the end viewing is done along a longitudinal axis. Thus, this rejection should be withdrawn.

35 USC 102 Rejections

I. Ayres

Claim 34 is rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 3,906,932 to Ayres ("Ayres"). Applicants respectfully traverse this rejection because Ayres does not describe each and every element of claim 34. Ayres does not disclose a drug delivery device, as the needle 40 is intended to puncture a stopper of a test tube (Fig. 5), not to deliver a drug. Thus, Ayres also does not disclose a catheter or syringe having a needle connected to a distal end thereof. Ayres describes a needle 40 having a opposed bevel faces 12 and 14 that are angled towards each other so that flat tips 16, 18 form an hourglass shape when viewed from the distal end, along a longitudinal axis (Fig. 4). Thus, although the opening at the distal end, may appear to have a U-Shape when viewed from the side, it does not have a U-shaped opening when viewed along the longitudinal axis from the distal end, as amended claim 34 states. For at least these reasons, claim 34 and all claims dependent therefrom, are not anticipated by Ayres.

II. Larson

Claims 1, 2, 5, 13, 15-18, 20, 22, 36, 41, 45 and 46 are rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 4,020,837 to Larson ("Larson"). Applicants respectfully

traverse this rejection because Larson does not describe each and every element of the claims. Larson describes a hollow piercing tip for vial stoppers having a sharpened tip end 12.

A. Claims 1, 2 and 5

Larson does not disclose a drug delivery device, as the needle structure 10 is only intended to puncture a seal of a medicament vial, not to deliver a medicament to a patient. Furthermore, although Larson does disclose a needle, the distal opening of the needle does not have a smaller cross-sectional area than a section of the shaft proximal to the distal end. Center bore 22 has the same projected area at the distal end as it does throughout the whole shaft (Figs. 2 and 5). Although the wall portion 24 has bevels 18 and 20, these bevels do not change the cross-sectional area of the opening at the end, but only alter the thickness of the wall (Fig. 5). The Examiner refers to the projected area as 20+22, however 22 is the center bore and 20 is the inner partially annular bevel in the wall 24. Thus, 20 does not form part of the distal opening, but rather forms the wall defining the opening. Clarification of the Examiner's interpretation is respectfully requested. Furthermore, Larson does not disclose the distal-most end is a curvilinear blunt tip. The tip of the needle extension 16 is described as sharpened tip 12. Blunt edge 30 forms part of the sharpened tip, along with bevels 18 and 20. However blunt edge 30, cannot be construed to be a curvilinear blunt tip, as the Examiner asserts. For at least these reasons, claim 1 and all claims dependent therefrom, are not anticipated by Larson.

With respect to dependent claim 2, Larson does not disclose a distal end having opposing first and second surfaces, wherein the first surface is indented towards the second surface to form a concavity on an outer potion of the first surface. According to the American Heritage Dictionary, a concavity has a surface curved like the inner surface of a sphere. Larson describes a beveled surface 18, which means a straight surface angled at a certain degree, as shown in Fig. 5. The surface of the needle in Larson has no curve and thus cannot form a "concavity". Thus, for at least these reasons, claim 2 is not anticipated by Larson.

B. Claims 13, 15, 16, 22, 23, 45 and 46

Larson does not disclose a method of delivering a therapeutic agent to a target site, or a method of collecting a fluid sample from a body, as recited in claims 13 and 22 respectively. As discussed above, Larson does not disclose a needle with a concavity on the outer surface thereof,

or a distal opening having a projected cross-sectional area smaller than a section of the shaft proximal to the distal end. Furthermore, the device of Larson is not used with the human body. Thus, Larson does not describe the steps recited in claim 13 of puncturing a body tissue or delivering a therapeutic to a target site of a body though the needle or the steps recited in claim 22 of inserting the needle into a fluid containment site of the body, and creating a vacuum in the drug delivery device to collect a fluid sample from the fluid containment site of the body. The Examiner fails to address these steps. Furthermore, Larson only describes puncturing a stopper of a medicament vial and is specifically designed to have a strength to puncture the seal, thus it would not be obvious to use such a device to puncture body tissue. For at least these reasons, claims 13 and 22 and all claims dependent therefrom are not anticipated by Larson.

With respect to dependent claim 15, 16, 23, 45, 46, the Examiner does not address any of these limitations. Larson does not disclose delivering a therapeutic to any target site by any method, let alone a specific target site as recited in claims 15, 45 and 46 or the specific delivery method as recited in claim 16 also is not disclosed. Additionally, since Larson does not disclose collecting any fluid sample from the body, a specific fluid as recited in claim 23 also is not disclosed. For at least these reasons, claims 15, 16, 23, 45 and 46 are not anticipated by Larson.

C. Claims 17, 18, 20, 36 and 41

With respect to independent claims 17 and 36, Larson does not disclose a needle with a concavity on the outer surface thereof, or a distal opening having a projected cross-sectional area smaller than a section of the shaft proximal to the distal end, as discussed above. For at least these reasons, claims 17 and 36 and all claims dependent therefrom are not anticipated by Larson.

III. Ferguson

Claim 36 is rejected under 35 U.S.C. 102(b) as allegedly anticipated by US Patent No. 2,560,162 to Ferguson ("Ferguson"). Applicants respectfully traverse this rejection because Ferguson does not describe each and every element of claim 36. In Ferguson, the heel portion of the needle point is depressed at 15, however the portion is evenly depressed as can be seen in the cross-sections of Figs. 4 and 6, and the portion 15 forms a hood-shaped section having a straight bottom edge when viewed from the distal end along the longitudinal axis (Figs. 4, 6). This

bottom edge forms a sharp tip that would core the tissue when used. Amended claim 36 states that a center of the concavity is depressed further than the sides of the concavity, thus yielding a U-shaped opening (see Figs. 1 and 2). For at least these reasons, claim 36, and all claims dependent therefrom, are not anticipated by Ferguson.

35 USC 103 Rejections

I. Ayres and Jansen

Claim 1 is rejected under 35 U.S.C. 103(a) as allegedly obvious over Ayres in view of US Patent No. 6,626,864 to Jansen et al. ("Jansen"). As discussed above, Ayres does not disclose a drug delivery device, a catheter, or a syringe. Jansen describes a safety shield system for prefilled syringes. Although the Examiner points to a passage (col 1, lines 26-28) in the background section that defines a needle as including various types of piercing elements, "whether sharp-pointed or blunt," there would be no need for a safety shield of Jansen's invention if the end of the needle was not pointed. Furthermore, there is no teaching, suggestion, or motivation to combine a device for puncturing a stopper of a test tube with a syringe for delivering a medicament to a patient. It would be obvious to one of ordinary skill in the art that different needle tips are necessary for puncturing tissue than for puncturing hard test tube stoppers. Thus, claim 1, and all claims dependent therefrom, is not obvious over Ayres in view of Jansen.

II. Ayres, Jansen and Alchas

Claims 3, 5, 39 and 42 are rejected under 35 U.S.C. 103(a) as allegedly obvious over Ayres in view of Jansen in further view of US Patent No. 4,537,593 to Alchas ("Alchas"). Ayres and Jansen do not describe all the limitations of claim 1, as discussed above, and Alchas cannot make up for these deficiencies. Alchas does not describe a needle having a distal opening and a distal-most end that is a curvilinear blunt tip. Rather Alchas describes a closed sharp pointed tip. Thus, claim 1, and all claims dependent therefrom, is not obvious over Ayres in view of Jansen in further view of Alchas.

With respect to claims 3 and 42, the Examiner uses Alchas for the disclosure of aperture 36, stating it would have been obvious to incorporate the aperture into the device of Ayres "in

order to vent air." However, there is no teaching, suggestion or motivation to use such a vent in Ayres. It would not be obvious to one of ordinary skill in the art to vent air from Ayres' device for puncturing test tube stoppers, since such an air vent could lead to undesirable contamination of samples housed in the test tube. For at least these reasons, claims 3, 5, 39 and 42 are not obvious over Ayres in view of Jansen in view of Alchas.

III. Larson and Alchas

Claim 44 is rejected under 35 U.S.C. 103(a) as allegedly obvious over Larson in view of Alchas. Larson does not describe all the limitations of claim 36, as discussed above, and Alchas cannot make up for these deficiencies. Alchas does not disclose a needle with a concavity on the outer surface thereof or any distal opening. Rather Alchas describes a straight needle with a closed sharp pointed tip. Thus, claim 36, and all claims dependent therefrom, is not obvious over Larson in view of Alchas.

With respect to claims 44, the Examiner uses Alchas for the disclosure of aperture 36, stating it would have been obvious to incorporate the aperture into the device of Larson "in order to vent air." However, there is no teaching, suggestion or motivation to use such a vent in Larson. It would not be obvious to one of ordinary skill in the art to vent air from Larson's device for puncturing vial stoppers, since such an air vent could lead to undesirable contamination of the medicament housed in the vials. For at least these reasons, claim 44, and all claims dependent therefrom, is not obvious over Larson in view of Alchas.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,
KENYON & KENYON LLP

Dated: October 22, 2008

/Jocelyn D. Ram/
Jocelyn D. Ram
(Reg. No. 54,898)

1500 K Street, N.W.
Suite 700
Washington, D.C. 20005
Tel: (202) 220-4200
Fax: (202) 220-4201